REMARKS

Status of the Claims

After entry of this amendment, claims 1-6, 10-11, 13-16, 27-28, 31-40 are pending. Claims 10, and 37 have been canceled without prejudice to future prosecution. Claims 1 and 27 have been amended to add the recitation "SEQ ID NO:23." New claims 39 and 40, directed to "SEQ ID NO:23" have been added." As explained below, SEQ ID NO:23 is a fragment (*i.e.*, amino acid residues 1-128) of Ra12. Support for these amendments and new claims can be found throughout the specification and claims as filed (*see, e.g.*, page 4, lines 6-7). Claim 27 has also been amended to incorporate the limitations of claim 29. Thus, no new matter is introduced by these amendments.

Amendments to the specification

As set forth in the amendment accompanying the substitute sequence listing under 37 C.F.R. §§ 1.821-1.825, the specification has been amended to correct a typographical error. The specification as filed describes SEQ ID NO:18 as amino acids 1-128 of SEQ ID NO:4. However, a review of the specification and sequence listing reveals that SEQ ID NO:18 is another Ra12-related sequence which was in the application as originally filed. Accordingly SEQ ID NO:23 which does constitute amino acid residues 1-128 of SEQ IS NO:4 has been added to the accompanying substitute sequence listing under 37 C.F.R. §§ 1.821-1.825. Support for a sequence which constitutes amino acids 1-128 of SEQ ID NO:4 is found throughout the specification as filed (*see, e.g.*, page 16, lines 2).

Rejection of the Claims Under 35 U.S.C. §112, second paragraph

Claims 6, 27-29, 31, and 34-38 stand rejected under 35 U.S.C. §112, second paragraph as allegedly as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse this rejection.

As set forth in MPEP § 2173.02, "[d]efiniteness of claim language, must be analyzed in light of (A) content of the application; (B) the teachings of the prior art; and (C) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made."

In the instant case, the specification adequately defines the terms or the terms are adequately understood to one of skill in the art, such that the claims are not indefinite under 35 U.S.C. §112, second paragraph. Several bases of indefiniteness were raised, and they will be discussed in turn.

1. Claim 6

Claim 6 has been rejected because the recitation "WT1" is allegedly unclear. As set forth in the specification, WT1 is an abbreviation for Wilm's tumor gene (*see,* page 2, line 22, as amended on February 26, 2003). Thus, Applicants respectfully submit that one of skill in the art would understand the term WT1 to refer to a polypeptide encoded by the Wilm's tumor gene. Accordingly, Applicants respectfully request withdrawal of this rejection.

2. Claim 27

Claim 27 has been rejected as allegedly unclear for omitting essential steps, *i.e.*, omitting the steps of isolating the expressed fusion polypeptide. In accordance with the Examiner's suggestion, claim 27 has been amended to add the recitation "purifying the fusion polypeptide from the host cell." Thus, Applicants respectfully submit that the claims are definite. Accordingly, Applicants urge the Examiner to withdraw the rejections under 35 U.S.C. § 112, second paragraph.

Rejection of the Claims Under 35 U.S.C. §102(b)

Claims 1, 3-4, 10, 13, 27-29, 21-32, 34, and 36-37 are rejected in various combinations as allegedly anticipated by Reed *et al.* (WO 97/09,429) or Reed *et al.* (WO 97/09,428). Each of these rejections is addressed below in the order presented by the Examiner.

For a rejection of claims under § 102(e) to be properly founded, the Examiner must establish that a single prior art reference discloses each and every element of the claimed invention. *See, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987). In *Scripps Clinic & Research Found. v. Genentech, Inc.*, 18 U.S.P.Q.2d 1001 (Fed. Cir. 1991), the Federal Circuit held:

> [A]nticipation requires that all of the elements and limitations of the claim are found with a single prior art reference. . . .There must be ***no difference*** between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.

Id. at 1010 (emphasis added). Anticipation can be found, therefore, only when a cited reference discloses ***all*** of the elements, features or limitations of the presently claimed invention.

1. Rejection of Claims 1, 3-4, 10, 13, 27-29, 21-32, 34, and 36-37 under 35 U.S.C. §102(b) as allegedly anticipated by Reed *et al.* (WO 97/09429)

Claims 1, 3-4, 10, 13, 27-29, 21-32, 34, and 36-37 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Reed *et al.* (WO 97/09429) (Reed '429). Applicants respectfully traverse this rejection.

In making the rejection, the Examiner alleges that Reed '429 discloses polynucleotides encoding fusion polypeptides comprising a *Mycobacterium tuberculosis* sequence linked to a non-*Mycobacterium tuberculosis* sequence. In particular, the Examiner alleges that the TbRa12 amino acid sequence set forth in SEQ ID NO: 67 of Reed '429 is identical to the amino acid sequence set forth in SEQ ID NO: 4 of the present application and concludes that Reed '429 anticipates the presently claimed invention.

As amended, the currently pending claims are drawn to a recombinant nucleic acid molecule comprising a Ra12 *Mycobacterium tuberculosis* polynucleotide sequence encoding SEQ ID NO:4, 17, 18, or 23 and a non-*Mycobacterium tuberculosis* polynucleotide sequence. Applicants respectfully assert that a perusal of SEQ ID NO:67 of Reed '429 and SEQ ID NO:4 of the present application reveals that these two sequences differ at amino acid position

111. More particularly amino acid 111 of SEQ ID NO:67 of Reed '429 is an asparagine residue. In contrast, amino acid 111 of SEQ ID NO:4 of the present application is a threonine residue. Therefore, SEQ ID NO:67 of Reed '429 is not the same as SEQ ID NO:4 of the presently claimed invention and Reed '429 does not disclose all of the elements of the claimed recombinant nucleic acid molecules that encode fusion polypeptides, wherein the Ra12 polynucleotide sequence consists of the separately patentable polynucleotide sequences encoding SEQ ID NOS:4, 17, 18, or 23. Therefore, Reed '428 does not anticipate the claimed invention. Accordingly, Applicants respectfully request that this aspect of the rejection under 35 U.S.C. §102(e) be withdrawn.

2. Rejection of Claims 1, 3, 10, 13, 27-29, 21-32, 34, and 36-37 under 35 U.S.C. §102(b) as allegedly anticipated by Reed *et al.* (WO 97/09428) (Reed '428).

Claims 1, 3, 10, 13, 27-29, 21-32, 34, and 36-37 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Reed *et al.* (WO 97/09428) (Reed '428). Applicants respectfully traverse this rejection.

In making the rejection, the Examiner alleges that Reed '428 discloses polynucleotides encoding fusion polypeptides comprising a *Mycobacterium tuberculosis* sequence linked to a non-*Mycobacterium tuberculosis* sequence. In particular, the Examiner alleges that the TbRa12 amino acid sequence set forth in SEQ ID NO: 66 of Reed '428 is identical to the amino acid sequence set forth in SEQ ID NO: 4 of the present application and concludes that Reed '428 anticipates the presently claimed invention.

As amended, the currently pending claims are drawn to a recombinant nucleic acid molecule comprising a Ra12 *Mycobacterium tuberculosis* polynucleotide sequence encoding SEQ ID NO:4, 17, or 23 and a non-*Mycobacterium tuberculosis* polynucleotide sequence. Applicants respectfully assert that a persual of SEQ ID NO:66 of Reed '428 and SEQ ID NO:4 of the present application reveals that the two sequences differ at amino acid position 111. More particularly amino acid 111 of SEQ ID NO:66 of Reed '428 is an asparagine residue. In contrast, amino acid 111 of SEQ ID NO:4 of the present application is a threonine residue. Therefore, SEQ ID NO:66 of Reed '428 is not the same as SEQ ID NO:4 of the presently

claimed invention and Reed '428 does not disclose all of the elements of the claimed recombinant nucleic acid molecules that encode fusion polypeptides, wherein the Ra12 polynucleotide sequence consists of the separately patentable sequences encoding SEQ ID NOS:4, 17, or 23. Therefore, Reed '428 does not anticipate the claimed invention. Accordingly, Applicants respectfully request that this aspect of the rejection under 35 U.S.C. §102(e) be withdrawn.

Rejection of the Claims Under 35 U.S.C. §103

Claims 1-6, 10, 13-16, 27-29, and 31 stand rejected under 35 U.S.C. §103(a) for alleged obviousness over Reed et al. (WO 97/09428) (Reed '428) in view of Wang *et al.* (U.S. Patent No. 6,509,448). Applicants respectfully traverse the rejection.

As an initial matter, Applicants note that Wang *et al.* is not available as a prior art reference to support a 103 rejection. As set forth in 35 U.S.C. §103(c):

> Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

The Reed '428, the Wang reference, and the present application are all assigned to the same entity: Corixa Corporation. At the time the inventions disclosed by the cited references and the present invention were made, the inventors were under the obligation to assign all patent rights to Corixa. Thus, as set forth in 35 U.S.C. §103(c) Wang *et al.* cannot be used to form the basis of a 35 U.S.C. §103 rejection. Accordingly, Applicants respectfully assert that the obviousness rejection based on Reed '428 and Wang *et al.* is improper and request withdrawal of the rejection.

Moreover, even if Wang *et al.* were available as a prior art reference to support a 35 U.S.C. §103 rejection, Applicants respectfully assert that that the rejection would be improper.

> As set forth in M.P.E.P. § 2143, "[t]o establish a *prima facie* case of obviousness, three basic criteria must be met. *First*, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. *Second*, there must be a reasonable expectation of success. *Finally*, the prior art reference (or references when combined) must teach or suggest all the claim elements. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)."

As explained above, the amended claims are drawn to a recombinant nucleic acid molecule comprising a Ral2 *Mycobacterium tuberculosis* polynucleotide sequence encoding SEQ ID NO:4, 17, or 23 and a non-*Mycobacterium tuberculosis* polynucleotide sequence. Also, as explained above, the amino acid sequence set forth in SEQ ID NO: 67 of Reed '428 is not the same as the amino acid sequence set forth in SEQ ID NO: 4 of the present application. In making the rejection, the Examiner alleges that Wang *et al.* disclose fusion proteins comprising *Mycobacterium tuberculosis* antigens. In particular, the Examiner alleges that SEQ ID NO:1864 of Wang *et al.* is a fusion of Ral2 and a non-*Mycobacterium tuberculosis* polypeptide wherein the Ral2 polypeptide is 5' to the non-*Mycobacterium tuberculosis* polypeptide and concludes that the Ral2 portion of SEQ ID NO;1864 of Wang *et al.* reads on SEQ ID NO:18 of the present application. As amended, the currently pending claims are drawn to a recombinant nucleic acid molecule comprising a Ral2 *Mycobacterium tuberculosis* polynucleotide sequence encoding SEQ ID NO:4, 17, 18, or 23 and a non-*Mycobacterium tuberculosis* polynucleotide sequence. Applicants respectfully assert that a perusal of Wang *et al.* reveals that the Ral2 portion of SEQ ID NO:1864 (*i.e.*, amino acids 8-137 of SEQ ID NO: 1864) is not the same as SEQ ID NO: 4, 17, or 23 of the present application.

Thus, the combination of Reed '428 and Wang *et al.* do not disclose all elements of the presently claims invention and the present invention is patentably distinct from the

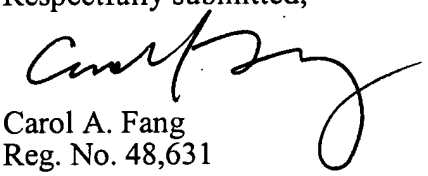
disclosures of Wang *et al.* or Reed '428. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 103(a).

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at 415-576-0200.

Respectfully submitted,



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